Food and Drug Administration, HHS

§173.55 Polyvinylpyrrolidone.

The food additive polyvinylpyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a polymer of purified vinylpyrrolidone catalytically produced, having an average molecular weight of 40,000 and a maximum

unsaturation of 1 percent, calculated as the monomer, except that the polyvinylpyrrolidone used in beer is that having an average molecular weight of 360,000 and a maximum unsaturation of 1 percent, calculated as the monomer.

(b) The additive is used or intended for use in foods as follows:

Food	Limitations
Beer	As a clarifying agent, at a residual level not to exceed 10 parts per million.
Flavor concentrates in tablet form	As a tableting adjuvent in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in concentrated liquid form.	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in liquid form	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vinegar Wine	As a clarifying agent, at a residual level not to exceed 40 parts per million. As a clarifying agent, at a residual level not to exceed 60 parts per million.

§ 173.60 Dimethylamineepichlorohydrin copolymer.

Dimethylamine-epichlorohydrin copolymer (CAS Reg. No. 25988-97-0) may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive is produced by copolymerization of dimethylamine and epichlorohydrin in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine, and in which the mole ratio of total amine to epichlorohydrin is approximately 1:1.
- (b) The additive meets the following specifications:
- (1) The nitrogen content of the copolymer is 9.4 to 10.8 weight percent on a dry basis.
- (2) A 50-percent-by-weight aqueous solution of the copolymer has a minimum viscosity of 175 centipoises at 25 °C as determined by LVT-series Brookfield viscometer using a No. 2 spindle at 60 RPM (or by another equivalent method).
- (3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlorohydrin. The epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Deter-

mination of Epichlorohydrin and 1,3-Dichloro-2-Propanol in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or http://www.archives.gov/ to: federal register/

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ibr locations.html.

- (4) Heavy metals (as Pb), 2 parts per million maximum.
- (5) Arsenic (as As), 2 parts per million maximum.
- (c) The food additive is used as a decolorizing agent and/or flocculant in the clarification of refinery sugar liquors and juices. It is added only at the defecation/clarification stage of sugar liquor refining at a concentration not to exceed 150 parts per million of copolymer by weight of sugar solids.
- (d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the Act, adequate